510(k) Summary of Safety and Effectiveness

14-Dec-05

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Official Contact: Dalia Givony – Manager Regulatory

Proprietary or Trade Name: CritiView

Common/Usual Name: Cardiovascular blood flowmeter

Fluorometer for clinical use

Classification Name: Cardiovascular blood Flowmeter (DPW)

Fluorometer for clinical use (KHO)

Device: CritiView

Predicate Devices: Tissue Spectroscope, Vital Medical – K992529 (Vital Medical became CritiSense).

Device Description:

The CritiView device carries out certain in-vivo, spectroscopic measurements and displays them as a trend. The parameters measured are blood flow change, blood volume change, and NADH concentration change. It is a multi-parametric monitoring device intended for the measurement of tissue metabolic state. The CritiView device consists of NADH Fluorometer and Doppler Flowmeter. The CritiView device is a modification of the predicate, Tissue Spectroscope (K992529).

Indications for Use:

CritiView is indicated for in-vivo monitoring of changes in NADH redox state and microvascular perfusion in tissue. Changes in the measured parameters, blood flow change, blood volume change, and NADH concentration change that provide information on tissue metabolic activity.

The CritiView uses a pencil style probe which is in contact with the tissue to be measured / monitored. The device may be used up to eight (8) hours per twenty-four (24) hour period.

Tissues which may be monitored are brain, liver, kidney, intestine, testis, skin. Note that heart may not be used, as the heart beating motion may not provide a reliable probe contact surface.

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Patient Population:

The device is intended for the monitoring of tissue metabolic activity of hospitalized patients. i.e., neonate/infant, pediatrics, and adults.

Summary of Specifications:

	CritiView
Indications for use	In-vivo monitoring of changes in NADH redox state and microvascular perfusion in tissue. Changes in the measured parameters, blood flow change, blood volume change, and NADH concentration change that provide information on tissue metabolic activity.
Environments of use	Hospital – OR, ICU, Emergency Departments, High Dependency Units Institutions
Patient Population	Hospitalized patients - Neonate/infant, pediatrics, adults.
Contraindications	Same as Tissue Spectroscope
Laser Class	Class 1 Laser Device
Measurement Technique	Absorption, reflection and fluorescence spectrometry
Light Source & Wavelength	UV LED 375nm UV LED 375nm NIR Laser Diode 785nm
Means for light transmission	In-vivo, fiber optic probe
Measured parameters	1. Blood Flow [%] Doppler Shift 2. Blood Volume [%] of change 3. NADH concentration [%] of change
Power Requirements	110 to 240V ±10
Method of measurement / probe	Direct tissue contact / Pencil type probe
Duration of use	Eight (8) hours per twenty-four (24) hours period

Differences Between Other Legally Marketed Predicate Devices:

There are no significant differences between the CritiView and the predicate – Tissue Spectroscope, K992529.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2006

CritiSense Ltd.
c/o Mr. Paul E. Dryden
President
ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501

Re: K051145
Trade Name: CritiSense CritiView
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW and KHO
Dated: December 14, 2005
Received: December 15, 2005

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K051145

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Environment of use include – hospital – OR, ICU, Emergency Departments, High Dependency Units Institutions

Prescription Use XX
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051145